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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,493	10/07/2003	Glenn C. Zillmer	P-11086.00	5536

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
FLORY, CHRISTOPHER A	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/680,493	**Applicant(s)** ZILLMER ET AL.
	Examiner Christopher A. Flory	**Art Unit** 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☒ Claim(s) *5,20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/14/2005*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "10" and "12" have both been used to designate IMD (paragraphs [25], [35], [50] and [51]. Reference characters "12" and "14" have both been used to designate the patient (paragraph [50]). Reference characters "18" and "16" have both been used to designate the heart ([42]).

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "10" has been used to designate both the system and the IMD ([35]). Reference character "88" has been used to designate both sense amplifier and RV out ([46]). Reference character "92" has been used to designate both sense amplifier and LV out ([40]).

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 94.

5. The drawings are objected to because coronary sinus 24 (paragraph [36]) is mislabeled with reference character "22" in Figure 2.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: right atrium (RA) 28 should be labeled in Fig. 6.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

9. The abstract of the disclosure is objected to because the key concept outlining the invention, extra-systolic stimulation, is abbreviated "ESS" throughout the abstract without first being stated in its entirety. This could prove a hindrance to the layperson trying to comprehend the scope and purpose of the invention. Correction is required. See MPEP § 608.01(b).

10. The disclosure is objected to because of the following informalities: the proper application numbers for the cross-referenced applications should replace the general term "10/xxx,xxx." They are as follows:

a. (Atty. Dkt. P-11155.00) → 10/680,528
b. (Atty. Dkt. P-11548.00) → 10/680,462
c. (Atty. Dkt. P-11354) → 10/680,494
d. (Atty. Dkt. P-11193) → 10/680,695
e. (Atty. Dkt. P-11438.00) → 10/692,990
f. (Atty. Dkt. P-11359.00) → 10/703,956

Appropriate correction is required.

11. The disclosure is objected to because of the following informalities: typographical error in paragraph [8] which reads "tissue proximate to electrodes typically become

polarized" should be corrected to read –tissue proximate to electrodes typically *becomes* polarized—as the verb 'becomes' refers to the singular noun 'tissue' and not the plural 'electrodes'.

Appropriate correction is required.

12. The disclosure is objected to because of the following informalities: paragraphs [34] and [36] include ranges of reference numbers, e.g. "each of electrodes 40-50," either not all of which are included or not all of which refer to the general group of components specified. The reference numbers should be listed separately so that only those numbers that refer to actual components of the invention are included. Appropriate correction is required.

Claim Objections

13. Claims 5 and 20 are objected to because of the following informalities: claim 5 contains the typographical error "an second ring electrode," which should be corrected to read –a second ring electrode--; claim 20 contains the typographical error "wherein the first set of electrode comprises," which should be changed to read –wherein the first set of electrodes comprises--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-11, 13-26, 28-47, and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennet et al. (US Patent 5,213,098; hereafter referred to as Bennet'098).

Regarding claims 16-24, 30-36, Bennet'098 discloses a medical device system (Figures 1 & 2) comprising a first set of electrodes (Fig. 2, electrodes 103 and 105) and a second set of electrodes (109 and 111) disposed on a first and second lead (leads 102 and 106) and attached to a medical device (pacemaker 100); wherein the system and electrodes are adapted to be chronically implanted within the patient and electrically coupled to the heart, more specifically the right ventricle (see Figure 2, where electrodes 103 and 105 are coupled to the right ventricle; column 8, lines 41-53); wherein the medical device is capable of detecting an arrhythmia based on electrical activity of the heart (column 4, lines 30-40, 66-69); and wherein the medical device is capable of sensing an evoked response resulting from the delivery of ESS (column 4, lines 10-29, 41-53).

It is noted that the limitations set forth in claim 20 that the first set of electrodes comprises a tip and ring electrode and the second set include two of the listed varieties do not distinguish the instant invention over the device in the Bennett'098 patent, which states that "leads 102 and 106 can carry either unipolar or bipolar electrodes as is well known in the art" (column 8, lines 48-49). All types of electrodes listed in claim 20 are well-known equivalents in the art and are capable of performing the functions of ESS arrhythmia detection. Therefore, the design choice of using a tip and ring electrode on a lead, which is a combination well-known in the art of cardiac pacing as evidenced by the references cited by the examiner on PTO-892, does not distinguish over Bennet'098.

Regarding claims 9 and 45, Bennett'098 shows a lead configuration with one lead near the outflow tract of the heart (lead 106 in right atrium, an outflow tract of the heart) and one lead in the ventricle near the apex of the heart (lead 102).

Regarding Claims 25 and 26, Bennet'098 shows a sense amplifier 146' connected to the second set of electrodes (Fig. 2, electrodes on atrial lead 106). "Far-field sensing" as it applies to the art of cardiac pacing generally refers to the oversensing of any electrical event that is not meant to be sensed, typically man-made or biological signals from another chamber of the heart, the exterior of the heart, or elsewhere in the body. The term applies to the art of dual-chamber pacemakers in referring to signals generated in the atrium (either biological or paced) that are sensed by the electrodes in the ventricle or vice versa. Although the Bennett'098 reference does not explicitly use the phraseology of "far-field blanking," it does disclose implementation of a dual-chamber pacing system in which a blanking period is enabled in Channel 1 (atrial electrodes) whenever a Channel 2 (ventricular) stimulus pulse is delivered, and a blanking period is enabled in Channel 2 whenever a Channel 1 stimulus is delivered (column 10, lines 41-63). These blanking periods after stimulation is delivered in the opposing chamber of the heart are taken to reference a far-field blanking as the term is commonly applied to the art. Bennet'098 provides examples that these intervals are programmable to periods between 0 and 20 ms, which are less than 300 ms (column 11 through column 13).

Regarding claims 28 and 29, Bennett'098 discloses a switch matrix (Fig. 4, isolation/protection circuit 224) that selectively couples and decouples the sense amplifier to the second set of electrodes (column 15, lines 23-51).

Regarding claims 1-8, 10-11, and 13-15, Bennet'098 discloses a method comprising delivering ESS to a chamber of a patient's heart via a first set of electrodes and sensing electrical activity of the chamber via a second set of electrodes (column 4, lines 10-68). The limitations imposed by claims 2-8, 10-11, and 13-15 have been addressed above in relation to the device claimed in the instant application and the rejection of the method claims follows the same argument. It is also noted that the Bennett'098 patent discloses the *device* of the instant application substantially as claimed and therefore is capable of implementing the *method* set forth in the instant application and is therefore not distinguished therefrom.

Regarding claims 37-44, 46-47, and 49-51, Bennett'098 discloses a number of computer readable media capable of storing executable instructions and performing the claimed methods. Microprocessor 120, RAM/ROM Units 124, 126 and 128; and digital controllers 132 and 210 are all known computer readable media. The further limitations imposed on the method stored on the computer readable medium by these claims in the instant application are rejected following the same reasoning applied to the device and method claims above.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 12, 27, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennet'098 in view of Darwish et al. (WO 01/58518).

Bennett'098 discloses the device and method of the instant application substantially as claimed and outlined above in paragraph 15. However, Bennett'098 does not disclose using a far-field blanking interval between approximately 30 and 120 milliseconds. In the same field of endeavor, Darwish et al. discloses evaluating the electrical response of the heart later than about 50 ms subsequent to application of pacing pulses in order to properly calibrate the system and determine one or more effective sites for subsequent application of paired pulses (page 6, lines 5-19)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the same 50 ms blanking period with the Bennett'098 device for the same advantages of proper administration of paired pulses (motivation to combine provided by Darwish et al., page 6, lines 5-19).

19. Claims 12, 27 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennet'098 in view of Mika et al. (US Patent 6,424,866).

Bennett'098 discloses the device and method of the instant application substantially as claimed and outlined above in paragraph 15. However, Bennett'098 does not disclose using a far-field blanking interval between approximately 30 and 120 milliseconds. In the same field of endeavor, Mika et al. discloses a delay interval $\Delta T4$ of 60 ms before delivering a pacing pulse following a cardiac depolarization or pacing stimulus in order to aid in reducing the probability of delivering an improperly timed non-excitatory pacing signal due to noise and to prevent delivery of multiple pacing signals within a single cardiac beat cycle (column 2, line 20 through column 10, line 5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a blanking period of 60 milliseconds (between 30-120 ms) with the Bennett'098 device in order to achieve the same benefits of reducing the probability of delivering improperly timed non-excitatory pacing signals (motivation to combine provided by Mika et al., column 2, line 20 through column 10, line 5).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

George Manuel
Primary Examiner